

GENERAL AGREEMENT ON

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TARIFFS AND TRADE

Limited Distribution

REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING

UNITED STATES OF AMERICA

The following notification has been received from the delegation of the United States of America in response to the Questionnaire on Import Licensing Procedures.¹ This comprehensive notification replaces and revises the United States' previous replies, contained in documents L/5131 and corrigenda, L/5640/Add.5 and L/5640/Add.22 and Corr.1.

Changes to the previous texts are indicated by asterisks and underlining where appropriate.

¹Annexed to L/5640/Rev.3

UNITED STATES LICENSING NOTIFICATION

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The following documents have also been supplied² to the Secretariat and may be consulted in the Trade and Finance Division (Room 3063, Centre William Rappard):

Section 5

United States Department of Energy, New Policy Guidelines and Delegation Orders on the Regulation of Imported Natural Gas, February 17, 1984;

Federal Register, September 6, 1984: Department of Energy, Import and Export of Natural Gas, New Administrative Procedures; Publication of Final Rule.

Section 7

Federal Register, October 29, 1985, February 7, 1986, March 25, 1986, May 13, 1986, and August 11, 1986: Department of Justice, Drug Enforcement Administration, Schedules of Controlled Substances, Temporary Placements of various substances;

Code of Federal Regulations, Title 21, Food and Drugs, Part 1300 to End, Revised as of April 1, 1986.

Section 9

United States Nuclear Regulatory Commission, Rules and Regulations, Title 10, Chapter 1, Part 110: Export and Import of Nuclear Facilities and Materials.

²in English only

1. Department of Agriculture: Plants and Plant Products

Outline of the system

- * 1. Import permits are required for the importation of most plants and plant products, to protect against introduction of pests and disease. Permits are also required for the import, export or re-export of territorial plants that are on the endangered species list.

Purposes and coverage

- * 2. Permits are required for:
 - plants and plant products for or capable of propagation
 - fruits and vegetables
 - grains
 - cut flowers
 - cotton and cotton covers
 - sugar cane bagasse
 - broom corn and broom straw
 - certain rice products
 - bags, bagging, brassware and wooden screens used to contain and transport plants
- 3. The permit system applies to products coming from all countries.
- * 4. The permit system is not used to restrict the quantity or value of imports, but to protect agricultural entry of plant pests and disease, and to protect endangered plant species.
- * 5. The permit system is a statutory requirement of the Plant Quarantine Act, 7 USC 154. The law specifies broad categories for the permit system. The Endangered Species Act and the Convention on International Trade in Endangered Species establishes a permit system for certain plants on the endangered species list.

Procedures

- 6. Not applicable.
- 7. (a) The amount of time in advance of importation within which a permit must be applied for is not specified in the legislation. However, a reasonable period of time must be allowed for permit issuance.
 - (b) A permit cannot be granted immediately on request.
 - (c) There are no limitations as to the period of the year during which permit applications may be made.

* / Indicates modification of previous submission (L/5131) noted in language underlined

- (d) Permit applications are effected by one office, U.S. Department of Agriculture, Permit Section, Room 635, 6505 Belcrest Road, Hyattsville, Maryland 20782. The application is not passed on to other organs for visa, note or approval, and the importer does not have to approach more than one administrative organ.
8. There are no circumstances other than failure to meet ordinary criteria under which a permit may be refused. Reasons for refusal are given to the applicant. No appeal procedures are specified in the legislation.

Eligibility of importers to apply for license

9. All persons, firms and institutions are eligible to apply for licenses. There is no registration fee. There is no published list of authorized importers.

Documentational and other requirements for application of license

- * 10. The information required in applications is set forth in the PPQ Form 587 and in the import permit form for endangered plants.
11. The only documentation required for actual importation are those routinely required for all imports. For most plants and plant products a phytosanitary certificate must accompany the shipment.
- * 12. There is no licensing fee or administrative charge. There is a \$70.00 fee per permit for endangered plants.
13. No deposit or advance payment is required in connection with the issue of permits.

Conditions of Licensing

- * 14. Permits are valid for five years, and they can be extended by reapplication. The permit for endangered plants is valid for two years.
15. There is no penalty for non-utilization of a permit.
16. Permits are not transferrable between importers.
17. There are no other conditions attached to the issuance of a permit other than for plants requiring post-entry growing.

Other procedural requirements

18. There are no other administrative procedures required prior to importation.
19. Not applicable.

*/ Indicates modification of previous submission (L/5131) noted in language underlined

2. Department of Agriculture: Sugar

1. Presidential Proclamation 4941 of 5 May 1982 amended Headnote 3 of sub-part A part 10 to Schedule I of the Tariff Schedules of the United States (TSUS) to modify import quotas for raw and refined sugar on a country-by-country basis. Regulations were issued for a voluntary certificate of eligibility system for imported sugar from quota countries on 11 August 1982. The certificate system is separate and distinct from the import quotas for sugar. For those countries that agree to participate in the system, the certificate must be presented to the U.S. Customs officials to obtain entry of sugar into the United States for consumption. If a country does not participate in the program, no certificate shall be required.

Pursuant to authority granted in Proclamation 4941, a separate quota for specialty sugars was established on June 23, 1983, for those countries not allocated a base sugar quota, with a maximum quota for each country of 80 short tons.

Under 7 CFR 6.100, 7 CFR 6.200-6, and 7 CFR 6.120-6.130, regulations were established to permit quota-free sugar imports under licenses for sugar re-exported in refined form or in sugar-containing products, and for sugar used to produce polyhydric alcohol.

2. The products covered by the certificate of eligibility are sugars, syrups and molasses described in TSUS 155.20 and 155.30. Specialty sugar certificates are issued for those sugars in TSUS 155.20 and 155.30 which: (1) are not commercially produced in the United States nor are readily available from domestic sources; (2) are the product of countries with no base sugar quota allocation; and (3) require no further processing. Licenses are issued for quota-exempt sugars in TSUS 155.20 and 155.30 which are: (1) used for the production, other than by distillation, of polyhydric alcohol except that used as a substitute for sugar in human food, or (2) re-exported in refined form or in sugar-containing products.
3. The certificate of eligibility system applies to those countries that agree to participate in the system and from which sugar is imported under quotas as authorized by Headnote 3 of sub-part A part 10 to Schedule I of the Tariff Schedule of the United States (TSUS).

Certificates for imports of specialty sugars apply to those countries in Headnote 3 (c) (ii) of Schedule I of the TSUS. Licenses for quota-exempt sugar are applicable to imports of sugar from all countries.

4. The purpose of the certificates of eligibility is to facilitate reasonable and orderly access to the United States sugar market for those countries to which a quota allocation has been given and to promote orderly marketing and distribution of sugar within the United

States. The purpose of the quota for specialty sugar is to meet the extremely limited demand for this product. Licenses for quota-exempt sugar are intended to increase the utilization of excess domestic capacity and improve employment in refining and related industries.

5. The certificates of eligibility are issued under 15 CFR 20112. The certificates for specialty sugar are issued pursuant to 15 CFR Part 2013. The regulations governing licenses for the importation of sugar exempt from quota are under 7 CFR 6.100-6.112, 7 CFR 6.200-6.214 and 7 CFR 6.120-6.130. Authority exists to suspend each of these systems whenever it is determined that such action is appropriate. Notice of such suspension shall be published in the Federal Register.
6. (a) Information on the allocation of quotas, and on the certificates and licensing system is published in the Federal Register, press releases from the Office of the United States Trade Representative, and the United States Department of Agriculture reports. In addition, the allocation of quotas on a country-by-country basis is also published under Headnote 3 sub-part A part 10 Schedule I of the TSUS.
- (b) The sugar import quota for raw and refined sugar is determined annually for a period of time as determined by the Secretary of Agriculture and announced by the fifteenth day of the month preceding the calendar quarter for which the quota will be in effect. The annual quota for specialty sugars of 2,000 short tons is announced at the same time as the quota for raw and refined sugar. Certificates of quota eligibility are issued by the Secretary of Agriculture to the participating countries to coincide with the applicable quota year. Certificates for importing specialty sugars are likewise issued to imports to coincide with the quota year. Licenses issued for quota-exempt sugar are not subject to the quota year limitations.
- (c) Certificates of eligibility are issued by the Secretary of Agriculture to participating foreign countries. The foreign country in turn executes and issues these certificates to a shipper or consignee of a cargo of sugar destined for the United States. For those participating countries, sugar is allowed entry only if a valid and properly executed certificate of eligibility is presented at time of entry to the appropriate customs official.

Certificates for specialty sugar are issued to importers by the Foreign Agricultural Service (United States Department of Agriculture) if sufficient evidence has been provided to make a reasonable determination that the sugar fits the definition of specialty sugar. Importers must apply for certificates for specialty sugar each quota year and any unused portion of a country's specialty sugar quota may not be carried over into the next quota year. The certificate is presented to the appropriate customs official at the time of entry.

Licenses for sugar imports exempt from quotas are issued to United States sugar refiners, United States sugar manufacturers using refined sugar for re-export in sugar-containing products, and United States manufacturers of polyhydric alcohol. A summary of transactions form (balance sheet showing charges and credits under the license) must be presented to the appropriate customs official at the time of entry. For quota-exempt sugar used in the production of polyhydric alcohol, a license is presented to the customs official at the time of entry.

- (d) Not applicable.
- (e) Not applicable.
- (f) Not applicable.
- (g) The United States Department of Agriculture administers the licensing and certificate systems.
- (h) The certifying authority designated by the participating country issues certificates of eligibility to the shipper or consignee of sugar. The maximum quantity of sugar to be shipped with each certificate shall not exceed 10,000 short tons.

Speciality sugar certificates are issued to importers on a first-come first-served basis. Subject to quota availability, an unlimited number of shipments may enter under a given certificate and the certificate may cover more than one type of specialty sugar. Issuance of a certificate does not guarantee entry if the specialty sugar quota is already filled.

The maximum quantity of sugar that can be entered under a quota exempt license for re-export in refined form cannot exceed 50,000 short tons at any time. As sugar is re-exported, however, a quantitative amount may be imported equal to the amount that has been re-exported. Licenses for quota exempt sugar for the production of polyhydric alcohol are issued to manufacturers of polyhydric alcohol from sugar for a period of up to one year. The maximum amount of sugar which may be entered under the license cannot exceed the anticipated requirements of the manufacturer.

Two types of licenses are issued to manufacturers for importing quota-exempt sugar to be used for re-export in sugar-containing products: (1) import licenses for the importation of quota-exempt raw sugar for refining by one or more United States refiners and/or; (2) user licenses for the transfer of refined sugar to a manufacturer from one or more United States refiners. The maximum amount which may be imported under an import license is 10,700 short tons of sugar, raw value basis, and a maximum of 10,000 short tons of sugar, refined weight basis, for a user license.

- (i) Not applicable.
 - (j) Not applicable.
 - (k) Licenses for quota-exempt sugar are issued only if: (1) a quantity of sugar equal to the sugar imported is re-exported in refined form, or (2) a quantity of sugar equal to the sugar imported or transferred is re-exported in a sugar-containing product.
7. Not applicable.
8. There are no provisions for refusing to issue certificates of eligibility, certificates for importing specialty sugars, or licenses for importing quota exempt sugar other than failure to meet the ordinary criteria.
9. All persons, firms and institutions are eligible to apply for certificates for specialty sugars. Only United States sugar refiners, manufacturers of sugar-containing products and the United States manufacturers of polyhydric alcohol can apply for licenses to import quota-exempt sugar. Import agents may be employed to import or export quota-exempt sugar. There is no registration fee or published list of authorized importers.
10. Each certificate of eligibility must be numbered and identified by the foreign country and must provide the following information: (1) quantity eligible to be entered; (2) name of shipper; (3) name of vessel; and (4) port of loading. The following information may also be included (if known): the name and address of consignee; expected date of departure; expected date of arrival in the United States; and expected port(s) of arrival in the United States.

Applicants for licenses to import sugar for re-export in refined form must apply in writing and must include: (1) name and address of the applicant; (2) license amount requested (not to exceed 50,000 short tons); (3) TSUS number and description of sugar to be imported; (4) name of firm that will establish a performance bond in favour of the United States Government on behalf of applicant, if such firm is not the applicant; (5) name of anticipated refinery; and (6) anticipated date of entry of sugar and export of refined sugar (if known). The license holder shall submit a certified statement of the polarization and weight of the imported sugar to be charged to the license.

Applicants for a license to import sugar for re-export in sugar-containing products must apply in writing and must include: (1) name and address of the applicant; license amount requested (not to exceed 10,000 short tons); (2) refined weight for a user license (or 10,700 short tons, raw value for an import license); (3) type of license requested (import and/or user license); TSUS number and description of sugar to be imported or transferred; (4) name of firm (if known) that will establish a performance bond in favour of the

United States Government on behalf of the applicant; if application is for a user license; (5) the name(s) of anticipated refiner(s) from which processed non-quota sugar will be received (if known). If the application is for an import license, a certification of the existence of the valid tolling contract(s), including name(s) of refiner(s) by which non-quota sugar will be processed. However, the Licensing Authority reserves the right to inspect a copy of such a tolling contract upon request; and (6) a description of sugar-containing products to be exported (if known) and estimated sugar content of such products.

Only manufacturers of polyhydric alcohol are eligible to receive an import license. Application for an import license must contain the following: (1) the name and address of the manufacturers; (2) statement of anticipated requirements of the manufacturer for sugar to be used in the production of polyhydric alcohol; (3) anticipated amount of sugar to be imported during the specified effective period; (4) the effective period of the import license (not to exceed one year); and (5) certification that the manufacturer shall use the quantity of sugar imported solely for the production of polyhydric alcohol, except polyhydric alcohols imported for use as a substitute for sugar in human food consumption.

Applications for certificates to import specialty sugar(s) must be in writing and must provide the following: (1) name and address of applicant; (2) anticipated quantity of imports; (3) the appropriate five-digit TSUS number; (4) a description of the specialty sugar(s) expected to be imported during the period of the certificate; (5) sufficient evidence that it is a specialty sugar(s); (6) anticipated consumers (if known) at time of application; and (7) anticipated date of entry (if known).

11. Quota sugar entered from those countries that agree to participate in the certificate system must be accompanied by a certificate which has been signed by the certifying authority in the country of origin and affixed with a seal or form of authentication.

A certificate issued by the Department of Agriculture authorizing the importation of specialty sugar(s) must be presented to the appropriate customs official at the time of entry.

Licenses issued by the Department of Agriculture for entry of sugar exempt from quota for re-export in refined forms, for re-export in sugar-containing products, or for use in the production of polyhydric alcohol must be presented to the appropriate customs official at the time of entry.

12. Not applicable.

- * 13. To enter the United States, sugar exempt from quota and entering under license must meet all the applicable customs bond requirements (19 CFR Parts 113,141-144) and be subject to a performance bond, except no bond is required for the quantity of any sugar entered for which an equal quantity of sugar has been exported prior to the date of entry or transfer of the sugar, and which has been credited to the license. A bond may cover imports or transfers made either during the period specified in the bond (term bond) or for a specified import or transfer (single entry bond). Only the refiner or manufacturer who imports the sugar or who will use the sugar may be the principal on a bond to cover such sugar to be imported or transferred. The amount of bond for sugar entering exempt from quota shall be three times the difference between the Market Stabilization Price (MSP) in effect for the appropriate period as announced by the Secretary of Agriculture and the daily spot No. 11 price as reported by the New York Coffee, Sugar and Cocoa Exchange multiplied by the weight of the sugar entered under license. In the case of a single entry/transfer bond, the difference between the number 11 price and the MSP shall be computed as of the last market day before the execution of the bond. In the case of a term bond, the No. 11 and MSP shall be computed quarterly based on the average difference between these prices for the twenty consecutive market days preceding the twentieth day of the calendar quarter for which the bond is in effect.

The appropriate customs official will release the obligation under bond for sugar imported by and amount computed in the preceding manner for a corresponding quantity of sugar credited to the license as having been exported in refined form or in a sugar-containing product or transferred in refined form to a licensed manufacturer participating in the sugar-containing product re-export program. The Department of Agriculture releases the obligation under bond for sugar transferred when a corresponding quantity of sugar is re-exported in sugar-containing products.

Customs releases the obligation under bond for sugar used in the production of polyhydric alcohol when a certificate of use has been filed within one month after the use of the sugar indicating that the sugar was used for the production of polyhydric alcohol.

Under the re-export program for refined sugar, if the license holder fails to export (or transfer to a license holder under the sugar-containing product re-export program) a quantity of sugar equal to the amount of sugar imported under license within three months of the date of entry, payment shall be made to the United States under the bond equal to the amount of sugar not offset by exportation. Under the re-export program for sugar-containing products, if a license holder fails to export within twenty-one months of the date of entry or within eighteen months of the date of a license transfer, payment shall be made equal to the monetary amount of sugar not offset

*/ Indicates modification of previous submission (L/5640/Add.22) noted in language underlined

by timely export. Failure to use the total amount of sugar for production of polyhydric alcohol production within 190 days of entry will require payment covering the quantity of sugar not used for the stated purpose.

14. The certificates of eligibility are valid only for the quota period for which they are issued. Under the re-export programs, licenses are valid for an indefinite period of time and are subject to only the quantitative limitation as mentioned above. The licenses issued under these programs will expire upon written notice to the license holders by the Licensing Authority. A certificate for specialty sugar is valid only for the quota year in which it is issued.
15. There is no penalty for non-utilization.
- * 16. Only licenses issued for re-exporting sugar in refined form can be transferred with the written permission of the Department of Agriculture provided that the refiner does not have a license. If an entry of sugar is made by an agent of the license holder, the agent shall produce for inspection to a U.S. Customs official a written authorization by the license holder designating such person to act as an agent for the license holder for the purpose of entering sugar.
17. There are no other conditions attached to issuing certificates.
18. No other procedures are required.
19. Not applicable.

*/ Indicates modification of previous submission (L/5640/Add.22) noted in language underlined

3. Department of Agriculture: Certain Dairy Products

Outline of the system

- * 1. Annual import quotas are imposed by Presidential Proclamation on certain dairy products whenever such imports are found to interfere or threaten to interfere with agricultural price support or other programs, or cause substantial reductions in the amount of such domestic products processed. Import licensing is used in administering the quotas for most of these products.

Purpose and coverage of the licensing

- 2. The licensing system covers the following dairy commodities: butter, certain dried milk products, malted milk and other articles of milk or cream, and certain cheeses.
- 3. The licensing system applies to dairy products coming from all supplying countries.
- 4. The licensing system is an administrative tool by which quantitative restrictions are allocated. No alternative methods have been adopted because the licensing system has proved to be a convenient and equitable means of allocating existing quotas and numerous domestic importers, while maintaining historical market shares among supplying countries.
- 5. The licensing system is not a statutory requirement. The authority to make such allocations was delegated to the Secretary of Agriculture by Presidential Proclamation 3019 of 8 June 1953. The requirement for import quotas under certain circumstances is provided by statute in Section 22 of the Agricultural Adjustment Act of 1933, as amended. Therefore, the system could not be abolished without legislative approval.

Procedures

- 6. (a) The procedures for making license application are published in the Federal Register. Information on quota levels, both global and individual country allocations, are published as Part 3 to the Appendix to the Tariff Schedules of the United States. The quota share allocated to each importer is, however, not publicly available (such information is considered as confidential business of the licensee).
- (b) Once established, the size of the annual quotas remains unchanged unless modified after full Section 22 review. Licenses cover the entire year and are issued for use beginning 1 January. Importers have to re-apply for licenses each year during a 90-day application period which begin August 1.

*/ Indicates modification of previous submission (L/5131) noted in language underlined

- * (c) Licenses are allotted to importers of dairy products regardless of whether they are producers of like products. See question 8 for an explanation of the steps taken to ensure that licenses allocated are actually used for imports. Unused allocations may not be added to the allocation of the succeeding year. The amounts voluntarily surrendered are then re-allocated to other eligible licensees. A list of names of licensed importers is mailed to all licensees each year. The list is available upon request.
 - (d) When a new quota for a dairy product is announced, the applicants have at least thirty days after the announcement of application procedures to submit applications and supporting documentation.
 - (e-f) Applications are processed as received. Calculation of the individual quota shares is completed after the November 1 deadline for applying. Licenses are issued for use beginning January 1.
 - * (g) Only the Import Licensing Group, Foreign Agricultural Service, United States Department of Agriculture, considers license applications on dairy products.
 - (h) Allocations of quota shares are made first to historical licensees, i.e., those who were importing prior to the imposition of the quotas. Allocation of the balance of the quotas is to non-historical and supplementary import licenses. Non-historical licensees are given priority from one year to the next provided they either use at least 85 percent of the license amount or voluntarily surrender that portion of the license amount they are not able to use. Eligibility requirements for supplementary licenses are the same as for non-historical licenses. Allocation to supplementary licenses are made to eligible applicants on a first-come, first-served basis except that the Government of countries that were assigned specific quotas as a result of the Trade Agreements Act of 1979 may name preferred importers for that portion of the quota not allocated to historical importers. (See reply to Question 9).
 - (i) Not applicable.
 - (j) Not applicable.
 - (k) Not applicable.
7. Not applicable.

*/ Indicates modification of previous submission (L/5131) noted in language underlined

8. Historical license eligibility can be revoked if the licensee fails to import against his quota share for two consecutive years or any three years within a five-year period. Licensees must use at least 85 percent of the license amount or voluntarily surrender the portion that he is unable to use, the license for that item for the next year will be reduced to the amount imported in the last year or one quarter of the Basic Annual Allocation whichever is greater. Non-historical licensees and supplementary licensees must use at least 85 percent of the license amount or voluntarily surrender that portion they are unable to use in order to be eligible for a license for that item next year. Revocation of historical licenses may be appealed within 30 days of the notification of revocation.

Eligibility of importers to apply for licenses

9. Bona fide importers or manufacturers of dairy products are eligible for import licenses. Historical license eligibility is established primarily on the basis of proof of importation of the item, for which application for license is made, during a specified representative period. The licensee is allocated a proportional share of the applicable quota bases on his trade during the representative period. Most quotas have a certain portion set aside for nonhistorical or supplementary licensees. An applicant for non-historical and/or supplementary licenses must establish that (1) he is currently in the business of importing or manufacturing cheese and/or cheese product; and (2) that he is not affiliated with any other person or firm holding import licenses.
10. Applications for historical licenses must submit proof of importation of the item, for which license application is made, during the specified representative period. In addition, for continuation of historical eligibility the applicant must certify each year that they will meet the requirements of the Import Regulation (form FAS-922). Applicants for non-historical and supplementary licenses must also submit certification as for historical licenses and proof of importation of at least 10,000 pounds or manufacturing of at least 100,000 pounds of cheese or cheese products in a USDA-approved plant (forms FAS-923 and FAS-924). Application may be submitted using the appropriate forms, or, if the forms are not available, in letter form.

Documentation and other requirements for application for license

11. At the time of the actual importation of a license number and control number taken from the licensee's copy of the license must be presented to the Port Director of Customs at the port where entry is made.
- * 12.-13. No fees or deposits are charged for or associated with the issuance of licenses. As of 1 January 1986, a fee of \$60.00 per license is charged.

*/ Indicates modification of previous submission (L/5131) noted in language underlined

14. Licenses are valid from the date of issuance through December 31 of that year. License validity cannot be extended into the next quota year.
15. See Reply to question 8.
16. Licenses are not transferrable between importers.
17. No other conditions are attached to the issuance of a license.

Other procedural requirements

18. All food imports are subject to the sanitation and labelling requirements of the Food, Drug and Cosmetic Act and the Fair Packaging and Labelling Act and the Federal Import Milk Act. These requirements are administered by the Food and Drug Administration.
19. Not applicable.

4. Department of Agriculture: Animals and Animal Products

Outline of the system

1. Import permits are required for the importation of certain animals and animal products, to protect U.S. livestock and poultry against introduction of disease.

Purposes and coverage

2. Permits are required for:
 - samples of certain dairy products
 - specimens of certain animal products for scientific use
 - samples of hay, straw and grasses
 - domestic farm livestock and other species that carry diseases that can affect farm livestock; notifies port veterinarian that an authorized shipment is imminent
 - poultry and hatching eggs
 - birds
3. The permit system applies to animals coming from all countries. Some variation results from whether or not the particular country is identified as unaffected by certain diseases.
4. The permit system is not used to restrict the quantity or value of imports, but to protect the domestic agriculture from entry of animal disease or pests.
5. The permit system is not a statutory requirement. The pertinent regulations are contained in 9CFR92 through 96; and in the following laws as codified: 21 USC 102 to 105, 111, 134, 135 and 19USC1306.

Procedures

6. Not applicable.
7. (a) The amount of time in advance of importation within which a permit must be applied for is not specified in the regulations.
(b) A permit cannot be granted immediately upon request. Prior review is required.
(c) There are no limitations as to the period of the year during which permit applications may be made.
(d) Permit applications are effected by one office. The application is not passed on to other organs for visa, note or approval, and the importer does not have to approach more than one administrative organ.
8. In general, there are no circumstances other than failure to meet ordinary criteria under which a permit may be refused. In the case of live animals, poultry, or birds, a permit for a particular time period

could be refused if space at a Quarantine Station is not available. Reasons for refusal are given to the applicant. No appeal procedures are specified in the legislation or regulations.

Eligibility of importers to apply for licenses

9. All persons, firms and institutions are eligible to apply for permits. There is no registration fee. There is no published list of authorized importers.

Documentational and other requirements for application of licenses

10. The information required in applications is set forth in VS forms 16-3, 16-3A, 16-28, 17-129, 17-130, 17-134, 17-135.
11. In the case of live animals and birds, copies of the import permit must accompany the shipment as well as a health certificate issued by the national veterinary service of the country of origin.
12. There is no licensing fee or administrative charge.
- * 13. Reservation fees for quarantine space are required for live animals and birds. The amount of the fee varies according to the animal and bird.
14. Permits for animal products vary in length of their validity, but are generally about 1 year. Permits for live animals and birds are valid for 7 to 60 days, depending on the type of animal. A new permit can be issued upon reapplication.
15. There is no penalty for non-utilization of a permit.
16. Permits are not transferrable between importers.
17. There are no conditions attached to the issuance of a permit, provided the applicant complies with the terms of the permit.

Other procedural requirements

18. There are no other administrative procedures required prior to importation.
19. Not applicable.

* / Indicates modification of previous submission (L/5131) noted in language underlined

5. Department of Energy: Natural Gas^{3/}*/

1. Outline of Systems

A. Authority

Imports of natural gas, whether by pipeline or as liquified natural gas (LNG), are regulated under Section 3 of the Natural Gas Act (NGA) (15 U.S.C. 717b), which provides that "no person shall... import any natural gas from a foreign country without first having secured an order... authorizing it to do so." Section 3 also provides that such orders shall be issued unless, after opportunity for hearing, it is found that the proposed importation will not be consistent with the public interest. Plenary authority over imports of natural gas rests with the Secretary of Energy. The Secretary has delegated the authority to "authorize" the import to the Administrator of the Economic Regulatory Administration (ERA) (Delegation Order No. 0204-111 (49 FR 6690, Feb. 22, 1984)).

^{3/} This section replaces L/5131, pages 9-13.

*/Imports of petroleum and petroleum products no longer are licensed by the U.S. Government, as a result of Proclamation 5141 (December 22, 1983), which terminated the licensing program established by Proclamation 3279, as amended.

In addition, the Secretary has delegated authority to the Federal Energy Regulatory Commission (FERC) to regulate the imported natural gas within the domestic gas system (Delegation Order No. 0204-112 (49 F.R. 6690, Feb. 22, 1984)). FERC responsibility includes the functions of approval or disapproval of the construction and operation of particular facilities, the site at which such facilities shall be located, and, with respect to natural gas that involves the construction of new domestic facilities, the place of entry.

B. Application, Filing, Public Notice, and Hearing

Import authorization proceedings are initiated by the filing of an application. The application is not a standard form, but an individual document incorporating the basic information and exhibits required by the rules covering such applications set forth in 10 CFR Part 590. After receipt of an application, ERA provides public notice of the filing in the Federal Register and solicits comments on the proposed import. Depending on the response to the notice and intervention by interested persons, ERA may act on the application immediately or institute further proceedings which can involve briefs of the issues,

oral argument, and in some cases a trial-type hearing. An opportunity to request additional procedures must be provided before an application can be denied.

C. Approval/Denial, Opinion and Order and Rehearing

After completing a record of the case, ERA can approve the import unconditionally, approve with conditions, or deny the import entirely. An ERA import decision is usually issued as an Opinion and Order, containing a narrative history of the proceedings, the issues considered, and the actual order itself. Any party potentially aggrieved by an ERA decision, may petition for rehearing of the decision. If rehearing is denied or if the decision on rehearing does not satisfy the aggrieved party, that party may petition for review of the decision by the United States Circuit Court of Appeals.

Purposes and Coverage of the Licensing

2. An order authorizing importation is required for any natural gas imported into the United States from any foreign country. Section 2 of the NGA defines natural gas as either natural gas unmixed, or any mixture of natural and artificial gas. (15 U.S.C. 717a)

3. The natural gas import system applies to any natural gas imported into the United States from any foreign country.

4. The purpose of the authorization system is to ensure that all importations of natural gas will be consistent with the public interest. (See Section 3 of the NGA). To satisfy the public interest standard, conditions such as volumetric limits, cost ceilings, or particular purchase contract arrangements have been imposed in the past on a case-by-case basis. These types of conditions also could be established by rule.

5. Federal authorization of natural gas imports is required by Section 3 of the NGA. The NGA specifies that natural gas only can be imported pursuant to an order granted under the Act. The Department of Energy Organization Act of 1977 (42 U.S.C. 7101 et seq.) specifies that the import of natural gas be regulated by the Secretary of Energy.

Procedures

6. The amount of natural gas to be imported is determined by the specific amount requested by a

particular applicant, but may be further limited by ERA. Volumetric limits have been imposed on a case-by-case basis in decisions in order to satisfy the public interest standard of Section 3 of the NGA.

7a. An application for authorization to import natural gas can be made at any time. Because of the magnitude of most natural gas import projects and the method of transportation (pipeline or LNG tanker), inadvertent imports do not occur.

b. In the case of natural gas, an import authorization can only be granted upon application and after an "opportunity for hearing" is provided. Under current procedures, the notice period can be abbreviated or occur later to permit authorization to obviate emergency situations (10 CFR 590.403). Emergency authorizations usually are of limited duration. Also, where no requests for additional procedures are filed, a "shortened proceeding" may be held (10 CFR 590.316).

c. Applications for license may be filed any time during the year.

d. Applications to obtain authorization to import natural gas are filed only with the ERA. In most cases

the applicant files a contemporaneous, but independent, application with the FERC covering those matters about the import project subject to FERC jurisdiction, pursuant to Delegation Order No. 0204-112. As noted in the response to Question 1 above, the FERC regulates the imported natural gas within the domestic natural gas system. Such responsibility includes the functions of approval or disapproval of the construction and operation of particular facilities, the site at which such facilities are to be located, and in the respect to imported natural gas that involves the construction of new domestic facilities, the place of entry.

8. The criteria applied by the ERA in considering a proposed natural gas import are set forth in DOE Delegation Order 0204-111 (49 F.R. 6690, Feb. 22, 1984). The ERA can deny an import only upon a finding that the proposal is not consistent with the public interest. Generally, all ERA orders, whether approving or denying an authorization, set out the factual and legal basis for the decision. Any party aggrieved by the decision may ask for rehearing of the decision pursuant to 10 CFR 590.501. If after rehearing an aggrieved party still is not satisfied, the party may then seek review of the decision by the U.S. Circuit Court of Appeals. (See Section 19 of the Natural Gas Act (15 U.S.C. 717r)).

Eligibility of importers to apply for license

9. All persons, firms and institutions are eligible to apply for authorization to import natural gas.

Documentational and Other Requirements for Application of License

10. Current rules do not establish or require any official application form for authorization to import natural gas. However, certain information should be supplied with the application, pursuant to 10 CFR 590.202.

11. Documentation of entry is solely the responsibility of the U.S. Bureau of Customs. Documents required upon actual importation of natural gas may include Customs Form 7501, an invoice showing the names of seller, buyer, unit price of merchandise and total price, and description of the merchandise including quantity, and evidence of the right to make entry.

12. A filing fee of U.S. \$50.00 is charged for each application for authorization to import natural gas (10 CFR 590.207).

13. There is no deposit or advance payment requirement associated with the issuance of an order to import natural gas.

Conditions of Licensing

14. The duration of a natural gas import authorization usually is specified in the ERA order granting the authorization and depends upon the particular circumstances of the proposed import. An import authorization can be extended upon application to ERA.

15. There is no penalty for non-utilization of an order to import natural gas.

16. Authorizations for imports or exports of natural gas are not transferable or assignable, unless specifically authorized by the Administrator of ERA.

17. Section 3 of the Natural Gas Act permits the attachment of conditions to an order authorizing the import of natural gas. The conditions, if any, which have been imposed in the past were determined on a case-by-case basis, and have been concerned, among other things, with limits on the price to be paid for gas, volumetric limitations, duration of the

authorization, reporting requirements, and contractual matters involved in the transaction.

Other Procedural Requirements

18. No other administrative procedures are required prior to importation.

19. Not applicable.

6. Department of Interior: Fish and Wildlife
(including Endangered Species)

Outline of system

- * 1. On August 25, 1980, the Service published final rules revising 50 CFR Part 14 (Importation, Exportation, and Transportation of Wildlife) to implement provisions of a number of wildlife laws enforced by the Service. As part of that rulemaking and under authority of the Endangered Species Act of 1979 (ESA), an import/export license requirement was imposed on any person who engages in business as an importer or exporter of fish or wildlife unless that person imports or exports certain excepted wildlife or falls within one of the categories of persons excepted from the requirement by the rules. The licensing provision was promulgated under section 9(d) of the ESA [16 U.S.C. 1538(d)] which provides that it is illegal for any person to engage in business as an importer or exporter of fish or wildlife (other than certain shellfish or fishery products) without first having obtained permission from the Secretary of the Interior. On March 24, 1974, the Service had published a notice granting temporary permission to all persons needing it. The import/export license was proposed on March 27, 1978. After two comment periods and two public hearings the Service retained the license requirement with certain exceptions in the final rules. The license requirement went into effect on January 1, 1981. On December 26, 1985, after publication of the proposed rule and extended comment period, the Service published a final rule amending the previous import/export licensing requirements, which became effective February 24, 1986.

- * The license requirement is found at 50 CFR 14.91. Licensees must: (1) pay \$250 per year; (2) pay an inspection fee of \$25 per shipment for each wildlife shipment imported into or exported from the United States. The first five shipments imported into or exported from the United States under an import/export license are included in the licensing fee; (3) importers or exporters of wildlife will pay fees for actual costs of inspections conducted at special times or locations at the shipper request; (4) keep certain records and retain them for five years; (5) allow Service inspection of records and inventories of imported wildlife; and (6) file any requested reports. Exceptions to the license requirement are found at 50 CFR 14.92. Certain persons excepted from the license requirement by 50 CFR 14.92(b) must still comply with the requirements of section 9(d) of the ESA, which are to : (1) keep records which fully and correctly disclose each importation or exportation of wildlife by them; (2) keep records which fully and correctly disclose the subsequent disposition by them of the imported or exported wildlife; and (3) allow Service inspection of records and inventories of imported wildlife.

* / Indicates modification of previous submission (L/5131) noted in language underlined

Purposes and coverage of the licensing

2. The licensing system covers all "wildlife" which by regulation means the same as "fish or wildlife", which is defined by 50 CFR 10.12 as follows:

The term "fish or wildlife" means any wild animal, whether alive or dead, including without limitation any wild mammal, bird, reptile, amphibian, fish, mollusk, crustacean, arthropod, coelenterate, or other invertebrate, whether or not bred, hatched, or born in captivity, and including any part, product, egg, or offspring thereof.

3. The licensing system applies to any person who "engages in business as an importer or exporter of wildlife". That phrase means for a person to devote time, attention, labor or effort to any activity for gain or profit that involves the importation or exportation of wildlife whether or not such person is an importer or exporter within the meaning of the customs laws of the United States.

Persons excepted from the license requirement by 50 CFR 14.92(b) include:

- (1) Common carriers;
 - (2) Customs house brokers;
 - (3) Public museums, or other public, scientific or educational institutions, importing or exporting wildlife for research or educational purposes and not for resale;
 - (4) Federal, State, or municipal agencies;
 - (5) Circuses importing or exporting wildlife for exhibition purposes only and not for purchase, sale, or transfer of such wildlife; and
 - * (6) Any person if the value [as declared on the Declaration for Importation or Exportation of Fish or Wildlife (Form 3-177)] of the wildlife that person imports and exports during a year totals less than \$25,000.
4. The licensing system is not intended to restrict the quantity or value of imports. The purposes of the license requirement are to: identify large commercial importers and exporters of wildlife, require records which fully and correctly disclose each importation or exportation of wildlife and the subsequent disposition of the wildlife by the importer or exporter, allow the Service to inspect records required to be kept and inventories of imported wildlife, remove repeat wildlife law violators from commercial wildlife trade, improve communications between the Service and commercial wildlife importers and exporters, and assist the Service in its effort to conserve endangered and threatened species and identify species which may be threatened or endangered.
 5. Section 9(d) of the Endangered Species Act of 1973 [16 U.S.C. 1538(d)] makes it unlawful "for any person to engage in business as an importer or exporter of fish or wildlife...without first having obtained

*/ Indicates modification from previous submission (L/5131) noted in language underlined

permission from the Secretary [of the Interior]". By regulation the term "permission" was treated as a grant of authority to require a license, but the license is not statutorily required. Exceptions to the license requirement can be created by regulation. Further, the coverage of the license can be broadened or narrowed by changing the definition of either "fish or wildlife" or the phrase "engage in business as an importer or exporter of fish or wildlife". It is possible to abolish this system without legislative approval.

Procedures

6. Not applicable.
7. (a) No time-limit is set for receiving an application in advance of importation. However, 50 CFR 14.91(a) states "it is unlawful after December 31, 1980, for any person to engage in business as an importer or exporter of wildlife without first having obtained a valid import/export license from the Director [of the Service]".
 - (b) Yes.
 - (c) No.
 - (d) Applications are submitted to and processed by Service law enforcement district offices. The Special Agent in Charge of each office has been delegated authority to issue licenses.
8. Applications must meet the provisions of 50 CFR 13.11 and 13.12. Under 50 CFR 13.21(b) a license may be refused if:
 - (1) The applicant has been assessed a civil penalty, has been convicted of any civil or criminal provision of any statute or regulation relating to the activity for which the application is filed, if such assessment or conviction, evidences a lack of responsibility;
 - (2) The applicant has failed to disclose material information required, or has made false statements as to any material fact, in connection with his application;
 - (3) The applicant has failed to demonstrate a valid justification for the permit and a showing of responsibility;
 - (4) The authorization requested potentially threatens a wildlife or plant population; or
 - (5) The Director finds through further inquiry or investigation, or otherwise, that the applicant is not qualified.

An applicant must be notified in writing if the application is denied and given reasons for the denial. If authorized in the notice of denial, the applicant may submit further information, or reasons why

the license should be granted. The final action by the Director is considered the final administrative decision of the Department of the Interior.

- * Under 50 CFR 14.93(e) a license may be refused if: The applicant owes any license fees or inspection fees for wildlife shipments at the time of application for renewal or of new application.

Eligibility of importers to apply for a license

9. (a) Not applicable.
- (b) All persons, firms, and institutions are eligible to apply for a license.

Documentational and other requirements for application of license

10. The following information is required:

- (1) Applicant's name, mailing address, and phone number;
- (2) Where the applicant is an individual, his date of birth, height, weight, color of hair, color of eyes, and sex; and business or institutional affiliation, if any, having to do with the wildlife to be covered by the license;
- (3) Where the applicant is a corporation, firm, partnership, institution, or agency, either private or public, the name and address of all partners and principal officers;
- (4) Location where the permitted activity is to be conducted;
- (5) Certification in the following language:

I hereby certify that I have read and am familiar with the regulations contained in Title 50, Part 13, of the Code of Federal Regulations and the other applicable parts in Subchapter B of Chapter I of Title 50, and I further certify that the information submitted in this application for a permit is complete and accurate to the best of my knowledge and belief. I understand that any false statement hereon may subject me to the criminal penalties of 18 U.S.C. 1001.

- (6) Desired effective date of license;
- (7) Date;
- (8) Signature of the applicant;
- (9) A brief description of the nature of the applicant's business as it relates to the importation or exportation of wildlife, e.g., "live animal dealer", "fur broker", "taxidermist", "retail department store", and "pet shop";

*/ Indicates modification to previous submission (L/5131) noted in language underlined

- (10) A statement of where books or records concerning wildlife imports or exports will be kept;
- (11) A statement of where inventories of wildlife will be stored;
- (12) Name, address, and telephone number of the officer, manager, or other person authorized to make records or wildlife inventories available for examination by Service officials; and
- (13) The anticipated dollar amount of wildlife to be imported or exporter during a calendar year.

A copy of the application has been attached.

- 11. An import/export license is only permission to engage in business as an importer or exporter of wildlife. Such a license is in addition to, and does not supercede, any other requirement established by law for the importation or exportation of wildlife.
- * 12. The license fee is \$250.
- 13. Applications must be accompanied by the license fee.

Conditions of licensing

- * 14. Licenses are valid for 1 year. They are automatically renewed and the licensee is billed for the renewal 90 days prior to expiration of the current license, unless the licensee advises the Service in writing to cancel the license.
- 15. If a licensee discontinues engaging in business as an importer or exporter of wildlife, the licensee must within 30 days mail the license and a request for cancellation to the issuing officer.
- 16. Licenses are not transferrable between importers. Agents under the direct control of, employed by, or under contract to the licensee may carry out the activities authorized by the license.
- 17. (a) Not applicable.
(b) In addition to the general conditions found in 50 CFR Part 13, under 50 CFR 14.93(d) licensees are subject to the following special conditions:
 - (1) The licensee shall, from the effective date of the license, keep such records as will fully and correctly disclose each importation or exportation of wildlife made by the licensee and the subsequent disposition made by the licensee with respect to such wildlife. The records must include a general description of the form of the wildlife, such as "live", "raw hides", or "fur garments"; the quantity of wildlife; in numbers, weight, or other appropriate measure; the common and scientific names; the country or place of origin of the wildlife, if known; the date and place of import

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or export; the date of the subsequent disposition of the wildlife; the manner of disposition, whether by sale, barter, consignment, loan, delivery, destruction, or other means; and the name and address of the person who received the wildlife pursuant to such disposition, if applicable;

(2) Licensees shall include and retain in their records copies of all permits required by the laws and regulations of the United States and any country of export or origin;

(3) Licensees shall maintain such books and records for a period of five years;

(4) Subject to applicable limitations of law, duly authorized Service officers at all reasonable times shall, upon notice, be afforded access to the licensee's places of business, an opportunity to examine the licensee's inventory of imported wildlife and the records required to be kept and an opportunity to copy such records;

(5) Licensees shall, upon written request by the Director, submit within 60 days of such request a report containing the information required to be maintained in the records of the licensee.

18. A license must comply with the requirements of 50 CFR Part 14 which apply to the importation, exportation, or transportation of wildlife generally. Further, a licensee importing or exporting a particular species may have to comply with other requirements found in 50 CFR Parts 10-23 and other State or Federal laws.
19. Not applicable.

7. Department of Justice: Controlled Substances

Outline of System

1. The system of import permits, declarations, and quotas is designed to restrict the importation of controlled substances to that quantity necessary to meet the medical, scientific or other legitimate needs of the United States, and to monitor the handlers of such substances. The system also establishes a method by which the United States can meet its international treaty obligations under the 1961 Single Convention Treaty on Narcotic Drugs and the Convention on Psychotropic Substances, 1971.

Purpose and Coverage of the Licensing

- * 2. In order to import any controlled substances, the importer must apply to and be approved by the Drug Enforcement Administration for the specific activity requested, annually. Upon registration approval, prior to importation, the importer must (a) apply for and receive a permit per specific importation for a Schedule I, Schedule II or narcotic controlled substances in Schedule III, IV or V, or (b) submit a specific import declaration per shipment for all non-narcotic controlled substances in Schedule III, IV, or V. The list of basic classes of substances covered by the Controlled Substances Act is listed in Title 21, Code of Federal Regulations, Section 1308.

*/ Revises L/5640, addenda 5 and 22.

- * In addition, the following substances have been added to the list:
1. Eight fentanyl analogs were temporarily controlled and placed in Schedule I for a one year period effective November 29, 1985 (50 FR 43698-43702, October 29, 1985).
 2. Nalmefene was removed from control under any schedule effective November 4, 1985 (50 FR 45815, November 4, 1985).
 3. Para-fluorofentanyl was temporarily controlled and placed in Schedule I for one year period effective March 10, 1986 (51 FR 4722-4724, February 7, 1986).
 4. The benzodiazepines quazepam and midazolam were controlled and placed in Schedule IV, effective March 25, 1986 (51 FR 10190-10191, March 25, 1986).
 5. The temporary placement of 3-methylfentanyl in Schedule I was extended for six months, effective April 25, 1986 (51 FR 15474, April 24, 1986).
 6. Dronabinol in sesame oil and encapsulated in soft gelatin capsules was rescheduled from Schedule I to Schedule II, effective May 13, 1986 (51 FR 17476-17478, May 13, 1986).
 7. The temporary placement of MPPP and PEPAP in Schedule I was extended for six months, effective August 12, 1986 (51 FR 28695-28696, August 11, 1986).

Other than opium or cocoa leaf, no Schedule I or II substance may be imported unless the Attorney General finds (a) an emergency exists in which domestic supplies are inadequate or (b) competition among domestic manufacturers is inadequate and will not be rendered adequate by registration of additional manufacturers.

3. In general the system applies to all importations of controlled drugs, regardless of country of origin. However, the Drug Enforcement Administration has recently taken action to impose limitations on imports of narcotic raw materials. A final rule published in the Federal Register on 18 August 1981, amended Section 1312.13 of Title 21, Code of Federal Regulations, relating to the issuance of import permits for narcotic raw materials. This amendment stated, in effect, that the importation of approved narcotic raw materials (opium, poppy straw and concentrate of poppy straw) into the United States shall be permitted only from Turkey, India, Yugoslavia, France, Poland, Hungary and Australia. At least 80 per cent of the narcotic raw material imported into the United States each year shall have as its original source Turkey and India. Except under conditions of insufficient supplies of narcotic raw materials, not more than 20 per cent of the materials imported annually shall originate in Yugoslavia, France, Poland, Hungary or Australia. This amendment became effective 17 September 1981.

*/ Revises L/5640 and addenda

4. The system is designed to restrict the quantity of imports of controlled drugs (not value) and to maintain a monitoring system. Previous systems were used prior to the CSA (effective May 1, 1971), however, the current system is mandated in law and based upon international drug treaties.
5. The system of registration of importers and the quota system are statutory requirements established in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (CS), Part C (Section 301, 302, 303, 306) and the import requirements established in the Controlled Substances Import and Export Act (Sections 1002, 1007 & 1008) (21 U.S.C. 822, 823, 826, 952, 957, 958) and implementing regulations. The CSA statutorily establishes criteria by which drugs are controlled in one of the five schedules subject to import requirements. The system required by statute cannot be abolished without legislative approval.

Procedures

6. a. Annual notice of publication of aggregate production quotas designed to account for the total needs of the United States (either through domestic manufacture or importation) for all Schedule I and II controlled substances is published in the Federal Register on or about July 1 of the year prior to that to which the quota applies. No quota is established for Schedule III, IV or V substances. Additional notice of regulations is published in 21 Code of Federal Regulations, Part 1300 to End.
- b. Quotas for legitimate need are determined on an annual basis, but determinations regarding importations are made at the time of individual applications.
- c. Import permits are issued only on application by registered importers who have demonstrated the legitimate need for the imported substance. Declarations are submitted as notice of import only for monitoring by DEA.
- d. Not applicable; individual determinations are made.
- e & f. Import applications are reviewed as received.
- g. DEA considers and approves all applications for importation of controlled substance. Copies of import permits are provided to the U.S. Customs Service for monitoring and certification purposes.
- h. Registration is based, in part, on security, records, history of violations, state approval. Import permits are based upon supply and legitimate need for the substance in the U.S.
- i. Not Applicable.
- J. Not Applicable.

- k. Controlled substances on permits may only be imported for legitimate needs of the U.S.
7. Schedule III, IV, and V non-narcotic controlled substances are subject to import declarations, and importers subject to registration.
- (a) Importation may be made only by approved, registered importers. An import declaration must be filed 15 days in advance of the proposed date of import. In special circumstances, the 15 days may be waived administratively.
- (b,c) Not applicable.
- (d) Yes, DEA
8. A registered importer can be refused an importation if he cannot demonstrate the need, in line with above criteria, in the United States. The importer may appeal the denial through a hearing with the Administrative Law Judge assigned to DEA matters.
- * 9. Imports are only approved for registered importers who must be inspected for adequate records, security, state approval, etc., prior to registration. The registration fee is \$125.00. Researchers are also allowed to import those substances for which they are registered to conduct research.

Documentational Requirements for Applications

10. The information required for an import permit is set forth in 21 C.F.R. 1312.12 and include (a) name, address of consignor, (b) foreign port of export, (c) U.S. port of entry, (d) dates of shipment, (e) name of carrier, (f) amount, and (g) importers allotment for the year.
11. Import permit.
12. No fee is levied per import permit.
13. No.

Conditions

14. Registration is annual. Permits are valid for six months.
15. Importation not pursuant to permit or declaration is subject to seizure, civil, and criminal penalties.
16. No.
17. No.
18. No.
19. Not Applicable.

*/ Revises L/5640 and addenda

8. Department of Treasury: Bureau of Alcohol, Tobacco and Firearms:
A. distilled spirits (beverages); wine and malt beverages

Outline of system

1. Producers, bottlers, wholesalers and importers of distilled spirits, wine and malt beverages are required to have permits, issued under the Federal Alcohol Administration Act, to engage in their respective businesses. Primary purposes of this requirement are to protect the consumer by oversight of labelling, advertising and other practices.

Purposes and coverage of the licensing

2. An importer's basic permit under the Federal Alcohol Administration Act is one of several different permits controlling the distilled spirits, wine and malt beverage industries.
3. The permit system applies to goods originating in and coming from all countries.
4. No. Intent of licensing is to ensure that commodities are packaged, marked, branded and labelled in conformity with the Federal Alcohol Administration Act.
- No
 - Not applicable
5. The permit system is a statutory requirement of the Federal Alcohol Administration Act, 17 U.S.C. 201 et. seq. 27 CFR Part 1, et. seq.
- Yes
 - No
 - No

Procedures

6. Not applicable
7. (a) Basic permits are issued usually within four weeks of application.
- (b) Not normally, however, under certain circumstances a license can be granted immediately on request.
- (c) No
- (d) Yes, consideration of license applications is effected by a single administrative organ.
- No
 - Not applicable

8. None

- The reasons for any refusal are given to the applicant in writing.
- In the event of refusal to issue a license, administrative appeals may be made through Director, ATF to the United States Court of Appeals.

Eligibility of importers to apply for license

9. (a) Yes
- (b) Not applicable
- Not applicable

Documentational and other requirements for application of license

10. Importer's basic permit. ATF Form 1631^{1/}
- Such supporting documentation as required
11. Certificate of Age and Origin (if issued by country of origin) and certificate of Label Approval.
12. No
- Not applicable
13. No
- Not applicable

Conditions of licensing

14. Continuing, unless revoked or surrendered.
- Not applicable
 - Not applicable
15. If inactive for two years, may be revoked.
16. No
17. (a) Not applicable
- (b) No

1/ A copy of this document is available for consultation in the Trade and Finance Division, Room 3063, Centre William Rappard.

Other procedural requirements

18. Payment of Special (occupational) Tax yearly under Internal Revenue Code: importer/wholesaler in liquors (spirits, wines and beer): \$255.00 - importer/wholesalers in beer: \$123.00 - 27 CFR Parts 194 and 251.
19. Not applicable

B. Department of Treasury: Bureau of Alcohol, Tobacco and Firearms: distilled spirits for industrial use (including alcohol for fuel use)

Outline of system

1. The Internal Revenue Code requires that producers, distributors and users of distilled spirits for industrial purposes have permits. Industrial alcohol is exempt from taxation if used as authorized by Law. The permit system is a means to control these authorized uses.

Purposes and coverage of the licensing

2. A License, as such, for the importation of alcohol for industrial use is not required. However, it cannot be received into this country except by a distilled spirits plant, permitted and bonded under the Internal Revenue Code. Each question answered is within this context.
3. All countries
4. See reply No. 1
 - No
 - Not applicable
5. 26 U.S.C. 5171, 5181
27 CFR Part 19
 - Yes
 - No
 - No
7. (a) Permits under the Internal Revenue Code are usually issued within four weeks from time of application.
(b) Not normally, however, under certain circumstances a license can be granted immediately on request.
(c) No

- (d) Yes
- No
 - Not applicable

8. None

- The reasons for any refusal are given to the applicant in writing.
- In the event of refusal to issue a license, administrative appeal may be made through the Director, ATF to the U.S. District Court.

Eligibility of importers to apply for license

9. (a) Yes
- (b) Not applicable
- Not applicable

Documentational and other requirements for application of license

- * 10. (a) Industrial Alcohol - Application for Operating Permit under 26 U.S.C. 5171(d) - ATF F 5110.25^{1/}
- (b) Fuel Alcohol - Application and Permit for Alcohol Fuel Producer under - 26 U.S.C. 5181; Form 5110.74^{1/}
- Such supporting documentation as required.
11. Ordinary commercial papers.
12. No
- Not applicable
13. No
- Not applicable

Conditions of Licensing

14. Continuing, unless revoked or surrendered.
- Not applicable
 - Not applicable
15. Permits are subject to revocation if not used within two years.
16. No

1/ Copies of these documents are available for consultation in the Trade and Finance Division, Room 3063, Centre William Rappard.

*/ Indicates modification from previous submission (L/5131/Add.1) as noted in language underlined

- 17. (a) Not applicable
- (b) No

Other procedural requirements

- 18. No
- 19. Not applicable

C. Department of Treasury: Bureau of Alcohol, Tobacco and Firearms:
firearms and ammunition

Outline of system

- 1. Under the Gun Control Act of 1968, the United States maintains a system of licenses and permits controlling the manufacturing, importing and dealing in firearms and ammunition. The Bureau of Alcohol, Tobacco and Firearms (ATF) administers the import controls along with the import controls established by the Arms Export Control Act of 1976.

Purposes and coverage of the licensing

- 2. See reply No. 1. Firearm means (a) any weapon (including a starter gun) which will or is designed to or may readily be converted to expel a projectile by the action of an explosive; (b) the frame or receiver of any such weapon; (c) any muffler or silencer; or (d) any destructive device. Antique firearms are exempt.
- 3. All countries (signatories to the GATT) except Czechoslovakia, Hungary, Poland and Romania. Imports from these four countries can only be for personal use, not for resale.
- 4. No. Generally, the purpose of the licensing system is to prevent the possession of firearms by persons falling within statutorily determined prohibited categories. A specific purpose of the import requirements, in addition to the above, is to ensure that machine guns, destructive devices, surplus military firearms, and other like firearms are not imported except for the use of governmental agencies.
 - No
 - Not applicable
- 5. 18 U.S.C., Chapter 44
26 U.S.C., Chapter 53
27 CFR Parts 178 and 179
 - Yes
 - No
 - No

Procedures

7. (a) License is issued within forty-five days after application.
Permit application is approved within ten days.

Permit can be approved immediately if license has been issued.
- (b) Permit can be issued immediately on request.
- (c) No
- (d) Yes
- No
 - Not applicable
8. None
- The reasons for any refusal are given to the applicant in writing.
 - In the event of refusal to issue a license, administrative appeal may be made to Director, ATF, further to United States District Court if desired.

Eligibility of importers to apply for license

9. (a) Yes
- (b) Not applicable
- Not applicable

Documentation and other requirements for application of license

10. Applications: (Forms 7 and 6)
- Application and Permit for Importation of Firearms, Ammunition and Implements of War (ATF Form 6, Part I)^{1/}
 - Release and Receipt of Imported Firearms, Ammunition and Implements of War (ATF Form 6A)^{1/}
11. None
12. Yes. \$50.00 per year importers of firearms or ammunition other than destructive devices or ammunition therefor - \$1,000.00 per year for importers of destructive devices or ammunition therefor.
13. No

^{1/} Copies of these documents are available for consultation in the Trade and Finance Division, Room 3063, Centre William Rappard.

Conditions of licensing

14. License: one year from date of issue.
Import Permit: six months from date of issue.

The validity of a license can be extended by renewal application for license and new application for import permit.

15. No
16. No
17. (a) Not applicable
(b) No

Other procedural requirements

18. No
19. Not applicable

- D. Department of Treasury: Bureau of Alcohol, Tobacco and Firearms:
arms, ammunition and implements of war

Outline of system

1. The United States maintains a system of registrations and permits to control the importation of arms, ammunition and implements of war. The law and regulations on these imports are administered by ATF in conjunction with the Gun Control Act of 1968. The Department of State maintains a similar system of controls relative to exports.

Purposes and coverage of the licensing

2. Persons engaged in the business of importing articles on the United States Munitions Import List must be registered. Actual importation is authorized by use of Form 6. Articles on the import list are articles that have significant military applicability.
3. All countries. Goods from certain countries (primarily centrally-planned economies) as determined by State Department are denied entry into the United States.
4. Primary purpose is to suppress international trafficking in arms.
- No
- Not applicable

5. Arms Export Control Act of 1976, 22 U.S.C. 2778
27 CFR Part 47
Executive Order 11432 (33 F.R. 15701)

- Yes
- Yes
- No

Procedures

7. (a) Approximately ten working days in advance.
- Yes

(b) Yes

(c) No

(d) Yes

- No
- Not applicable

8. None

- Yes

- In the event of refusal to issue a license, administrative appeals may be made through Director, ATF to United States District Court.

Eligibility of importers to apply for license

9. (a) Yes

(b) Not applicable

- Not applicable

Documentation and other requirements for application of license

10. ATF Forms 4587 and Form 6^{1/}

- None

11. ATF Forms 6 and 6A^{1/}

^{1/} Copies of these documents are available for consultation in the Trade and Finance Division, Room 3063, Centre William Rappard.

* 12. Fee for registration but not for permit.

Amount of the fee:

One year:	<u>\$250</u>	Four years:	<u>\$850</u>
Two years:	<u>\$500</u>	Five years:	<u>\$1000</u>
Three years:	<u>\$700</u>		

13. No

Conditions of licensing

14. Registration: one to five years
Permit: six months from date of issue

15. No

16. No

17. (a) Not applicable

(b) No

Other procedural requirements

18. No

19. Not applicable

E. Department of Treasury : Bureau of Alcohol, Tobacco and
Firearms: explosives

Outline of system

1. Manufacturers, dealers and importers of explosive materials are required by Law to be licensed to engage in their respective businesses. The primary purpose of this licensing system is to keep explosives out of the hands of persons prohibited by the Law from receiving, or possessing explosives and to insure the safe and secure storage of explosives.

Purposes and coverage of the licensing

2. Explosive materials are explosives, blasting agents and detonators. Permits are required of users who wish to buy in inter-State or foreign commerce. Licenses are required as stated in reply No.1:
3. All countries.

* / Indicates modification from previous submission (L/5131/Add.1) as noted in language underlined

- * 4. No. Purposes are to protect against the misuse and unsafe or insecure storage of explosive materials. See also reply No. 1.
 - No
 - Not applicable
 - No

- * 5. 18 U.S.C. Chapter 40 - 27 CFR Part 55
 - Yes
 - No
 - No

Procedures

- 7. (a) An application must be approved or denied within forty-five days after receipt. Usual turn-around time from receipt of application to issuance of license is thirty days.
 - (b) No, not usually. However, it could be done under extreme circumstances.
 - (c) No
 - (d) Yes
 - No
 - Not applicable

- 8. None
 - Yes, the reasons for any refusal are given to the applicant in writing.
 - In the event of refusal to issue a license, administrative appeals may be made through Director, ATF. Then, right of appeal to United States Court of Appeals.

Eligibility of importers to apply for license

- 9. (a) Yes
- (b) Not applicable
 - Not applicable

*/ Indicates modification from previous submission (L/5131/Add.1) as noted in language underlined

Documentational and other requirements for application of license

10. Application ATF Forms 6 and 6A^{1/}
- None
11. Proof to the United States Customs of licensed or permitted status furnished by importer or his agent. Explosives must be classified and marked per United States Department of Transportation standards.
12. Yes,
\$50.00 per year for license
\$25.00 per year for renewal
\$20.00 permit fee per year
\$10.00 permit renewal per year
13. No

Conditions of licensing

14. One year from the date of issue.
15. No
16. No
17. (a) Not applicable
(b) No

Other procedural requirements

18. No
19. Not applicable

^{1/} Copies of these documents are available for consultation in the Trade and Finance Division, Room 3063, Centre William Rappard.

9. Nuclear Regulatory Commission: Nuclear Facilities and Materials

Outline of systems

- * 1. The Nuclear Regulatory Commission (NRC) regulations governing the import of nuclear materials are published in 10 CFR 110^{1/}, pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. These regulations apply to all persons in the United States except that the U.S. Departments of Energy and Defense are not subject to the NRC's import licensing requirements.

The list of nuclear equipment and material subject to NRC import licensing authority covers Production and Utilization Facilities, Special Nuclear Material, Source Material, and Byproduct Material. These are defined in 10 CFR 110.2.

Although these items are subject to the NRC import licensing authority, most requirements for issuance of specific licenses for their import have been eliminated through the general licensing provisions contained in 10 CFR 100.27. Under the general license provisions, any person may import byproduct, source, or special nuclear material, other than 100 kilograms or more of irradiated fuel, if the consignee is authorized to possess the material, without the requirement for a specific import license. The general license in 10 CFR 110.27 requires the importer of special nuclear material to provide to the NRC advance notification of imports, where required according to 10 CFR 73.27.

A specific import license is required for the import of over 100 kilograms of irradiated fuel (spent special nuclear material).

Purposes and coverage of the licensing

- * 2. The list of items under NRC import licensing authority is found in 10 CFR 110.9.
3. The licensing requirements apply to goods originating in and coming from all countries.
4. The licensing is not intended to restrict quantity or value of imports. The primary purposes for licensing of imports are related to health and safety matters, controls over possession, use, distribution, manufacture and transport, and to considerations of inimicality to the common defense and security of the United States.

1/ A copy of this document is available for reference in the Trade and Finance Division, Room 3063, Centre William Rappard.

*/ Indicates modification of previous submission (L/5131/Add.2) noted in language underlined

- * Alternative methods of accomplishing the purposes of import licensing are considered and NRC's import licensing regulations take these into account, as appropriate. In addition, most specific import license requirements for byproduct, source and special nuclear materials, have been eliminated through the general licensing provisions contained in paragraph 10 CFR 110.27.
- 5. As mentioned in reply No. 1, the NRC regulations in 10 CFR 110 are issued pursuant to the Atomic Energy Act of 1954, as amended. The Nuclear Non-Proliferation Act of 1978 does not directly affect import licensing requirements. The legislation defines the products and facilities subject to licensing controls with minimum discretion in definitions left to administrative determination.

Procedures

- 6. Products are not restricted as to quantity or value of imports.
- 7. (a) There is no fixed period for submission of a license application in advance of importation, other than the times prescribed in 10 CFR 110 required for public notice of receipt of the application (see 10 CFR 110.70 and 10 CFR 110.82.) The Commission does have the prerogative for granting specific exemptions from the regulations in 10 CFR 110 under certain conditions (see 10 CFR 110.10) and this prerogative has been exercised on occasions to grant licenses within a short period of time.
- (b) A specific license would rarely be granted immediately upon request. The applicant should anticipate a review period of three to six weeks from date of application.
- (c) There are no limitations as to the period of the year during which the license application or importation may be made.
- * (d) For materials and production and utilization facilities, subject to Nuclear Regulatory Commission licensing authority, the NRC is the only agency with which the importer must correspond. For certain imports, the NRC refers applications to other interested federal agencies for review (usually to the Departments of State and Energy), although the final licensing responsibility remains with NRC. Because the Department of Commerce also has licensing responsibility for many items that are nuclear-related or dual-use in nature, NRC coordinates general policy and some specific cases with Commerce.

*/ Indicates modification of previous submission (L/5131/Add.2) noted in language underlined

8. No import license has been refused, to date. It is unlikely one would be refused for reasons other than failure to meet the ordinary (statutory) criteria. Reasons for refusal to issue would be made known to an applicant and there would be rights of appeal. The avenues open to the applicant are given in Sub-parts H, I, J, K, and L of 10 CFR 110.
- * 9. All persons are eligible to apply for an import license -- non-restrictive.

Documentational and other requirements for application of license

- * 10. Information required in a license application is set out in 10 CFR 110.30 and 110.31. There is no prescribed form. The usual submission is in letter form. The importer may support his application with other documents of his choosing. NRC may request additional information, if necessary, to conduct the licensing review required by applicable statutes.
11. The NRC does not require any documents for the importation, other than the import authorization itself (license). However, the customary forms required by other government agencies for import will be necessary (Customs Service and the Department of Commerce documents, for example). Certain reporting requirements are necessary when the transfer of nuclear material is involved, but these are not related to the import authorization.
- * 12. There is no fee or administrative charge for a license.
- * 13. There is no deposit or advance payment required for a license.

Conditions on Licensing

14. An import license is usually valid for a period of one year from the date of issuance but the validity date can be for a longer period if the applicant so requests and the NRC agrees. The license expiration date will be extended, in almost all cases, upon request by the licensee.
15. There is no penalty for failure to use a license.
16. A license may be transferred or assigned to another person only with the approval of the Commission.
17. A license often is conditioned with respect to transportation requirements, security provisions, and notification requirements.

* / Indicates modification of previous submission (L/5131/Add.2) noted in language underlined

Other procedural requirements for the import of nuclear materials

- * 18. Because many of the materials which can be imported under both specific or general NRC import licenses are considered hazardous and may be of strategic significance, other arrangements may be necessary in conjunction with their transportation. These arrangements may involve such things as physical protection, special handling procedures for health and safety purposes, or advance notice of pending receipt and are not part of the import authorization itself. These are general requirements placed on persons in the United States who transfer or receive specific types of materials, whether the shipment is a domestic one or from abroad.
19. The formalities for obtaining foreign currencies or its availability are not specified.

* / Indicates modification of previous submission (L/5131/Add.2) noted in language underlined

10. Department of Health and Human Services, Public Health
Service - Food and Drug Administration:
Biological Products

Outline of the system

1. Biological products and establishments are subject to licensing under Section 351 of the Public Health Service Act which requires the obtaining of both an establishment and product license by the domestic or foreign manufacturer prior to introduction of the product for marketing in inter-State commerce. The statutory authority is Section 351 of the Public Health Service Act (42 USC 262).

The following comments provided in answer to the questionnaire annexed to document L/5106 are based upon the singular licensing system for both foreign and domestic manufacturers.

Purposes and coverage of the licensing

- * 2. All biological products intended for use in man are licensed under Section 351 of the Public Health Service Act and included in the current Licensed Establishments and Products book, Publication No. FDA 85-9005.^{1/}
3. A computer printed listing includes the currently licensed foreign establishments and the products they are authorized to import.
4. Licensing does not restrict the quantity or value of imports. Its purpose is to assure that safe, pure, potent and effective biological products only are introduced for marketing in the country. Consideration of alternative methods has not been deemed necessary.
5. The statutory authority for licensing of biological products is Section 351 of the Public Health Service Act (42 USC 262). All products defined by the statute or by regulations (21 CFR 600.3)^{1/} promulgated thereunder require licensure. It is not possible for the Government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. No biological products are under the restrictions as to the quantity or value of imports.

^{1/} A copy of this document is available for reference in the Trade and Finance Division, Room 3063, Centre William Rappard.

^{*/} Indicates modification of previous submission (L/5131/Add.2) noted in language underlined

- * 7. (a) Application for product licensure may be applied for after the manufacturer has documented that the product is safe and effective. If such documentation and required data are complete at time of filing, approval can usually be accomplished following: (1) a determination that the establishment complies with applicable standards; (2) satisfactory testing of the product(s); and (3) administrative review of the application. No biological products may be imported until a license is issued and a license cannot be issued until safety and efficacy have been demonstrated. There is no provision for an abbreviated approval procedure for licensing of biological products.
- (b) No. See answer to question 7(a) above.
- (c) No.
- * (d) The Office of Biologics Research and Review (OBRR), Center for Drugs and Biologics, of the Food and Drug Administration has the sole responsibility for the approval of biological product licenses intended for use in man. No other administrative organs are required for the approval of imported biological products except for products of animal origin. See the response to question No. 18 - other procedural requirements.
- * 8. It is the practice of the OBRR to reject an initial submission of an application by a manufacturer if it is determined to be incomplete to such an extent that a technical and regulatory review cannot be performed. Also, after the initial submission, if a manufacturer fails to submit additional data and information needed for licensure, the Bureau will put the manufacturer on notice that his application will be placed in the Inactive Files unless he responds with the requested information and data within sixty days. Normally it is the practice of OBRR to give the applicant every opportunity to obtain a license, and so long as the manufacturer is making a sincere effort toward that goal, OBRR will keep the license application file open. However, 21 CFR 601.4(b) provides for the rejection of applications through the administrative procedure known as "denial of license" and provides for an appeal mechanism.^{1/}

Eligibility of importers to apply for license

9. All persons, firms and institutions are eligible to apply for licensure without restriction, provided they are the manufacturers of the product intended to be imported.

^{1/} A copy of this document is available for reference in the Trade and Finance Division, Room 3063, Centre William Rappard.

^{*/} Indicates modification of previous submission (L/5131/Add.2) noted in language underlined

Documentational and other requirements for application of license

10. A description regarding what is required to be submitted by the manufacturer for application for a biological product or establishment license is included in 21 CFR 601.2.^{1/}

Importers may act only as distributors of the licensed products in the country, but cannot perform any steps in the manufacture of the product.

11. For licensed biological products, documentation (i.e., labelling) that the product holds a valid United States license and OBRR lot release document (if the specific product is subject to lot release by the Food and Drug Administration).
12. There is no licensing fee or administrative charge for the importation of biological products.
13. There is no deposit or advance payment required with the issue of licenses.

Conditions of Licensing

- * 14. A license for a biological establishment or product remains valid until revoked at the request of the manufacturer or by reason of cause if such establishment or product does not meet current standards. The manufacturer is required to inform the agency of changes in products or establishments and the agency is required to perform inspections at least once every two years to validate the status of each firm.
15. In certain instances, revocation procedures may be instituted if the manufacturer fails to continue the production of the licensed product such that a meaningful inspection cannot be performed by the agency.
16. No. The holder of each license (manufacturer) must demonstrate the capability to prepare a safe, pure and potent product.
17. There are no quantitative restrictions on biological products. Proof of safety and efficacy as well as adequate manufacturing facilities and labelling are the major determinants for licensure.

Other procedural requirements

18. Yes. If biological products of animal origin (i.e., made from animals and intended for use in man) are to be imported, they must be accompanied by a Department of Agriculture, Animal Health Division permit as described in 21 CFR 12.23(d).^{1/}
19. Not applicable.

^{1/} A copy of this document is available for reference in the Trade and Finance Division, Room 3063, Centre William Rappard.

* / Indicates modification of previous submission (L/5131/Add.2) noted in language underlined